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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/567,899	08/10/2006	Ney Osvaldo Silva Filho	033794/307767	7174

826 7590 03/29/2007  
ALSTON & BIRD LLP  
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CHARLOTTE, NC 28280-4000

EXAMINER
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MI, QIUWEN

ART UNIT	PAPER NUMBER
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1655

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/29/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/567,899

Applicant(s)

FILHO ET AL.

Examiner

Qiuwen Mi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 11-14 and 19-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 15-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

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## **DETAILED ACTION**

### **Election/Restrictions**

Applicant's election without traverse of claims 1-10, and 15-18 in the reply filed on 2/15/2007 is acknowledged.

Claims 11-14, and 19-22 are withdrawn from further consideration as being drawn to nonelected inventions.

### **Claim Rejections –35 USC § 112, 1st**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-10, 17, and 18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Ventricular fibrillation cannot be prevented. It can be treated, but not prevented. There is no evidence that one could prevent ventricular fibrillation by consuming the claimed *Trichilia*

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*spp.* Unless Applicant can show on the record that ventricular fibrillation would be completely prevented in every instance, Applicant is requested to cancel prevention.

### **Claim Rejections –35 USC § 101**

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-10, 17, and 18 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either an asserted utility or a well established utility.

The claims recite preventing ventricular fibrillation. To prevent such a disease is not a credible utility. There is no evidence that ventricular fibrillation would be prevented in every instance, thus it is not a credible utility.

### **Claim Rejections –35 USC § 112, 2<sup>nd</sup>**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4,5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The tables in claims 4,5 are confusing and Applicant is required to write out the components in a single claim sentence. Also reciting “generic” and “preferred” is confusing. Applicant should recite one range for each component.

### **Claim Rejections –35 USC § 102**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1, 2, 8, and 18 are rejected under 35 USC § 102 (a) as being anticipated by Batista et al (WO 200296443).

Batista et al teach a method for treating acute myocardial infarction with a composition comprising *Trichilia catigua*, *Paullinia cupana*, and *Zingiber officinale* (see Abstract).

Since the claims 1, 2, 8, and 18 recite “prevent” ventricular fibrillation, it is not necessary that the one has ventricular fibrillation condition.

Therefore, the reference is deemed to anticipate the instant claim above.

### **Claim Rejections –35 USC § 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-8, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Andre et al (WO 200296441) and Sander et al (US 6,335,039).

Andre et al teach a method of using *Trichilia catigua*, *Paullinia cupana*, *Zingiber officinale* and a carrier (excipient) as vasodilators (page 2, lines 10-15).

Sander et al teach a method for producing vasodilation using *Trichilia catigua*, guarana (the same as *Paullinia cupana* , see the instant specification, page 2, 2<sup>nd</sup> paragraph ), Muirapuama (the same as *Croton moritibensis*, see the instant application, page 2, lines 10-15) (col 4, lines 15-45).

It is well known that it is *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. *In re Sussman*, 1943 C.D. 518; *In re Pinten*, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); *In re Susi*, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

Therefore, it would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to combine the inventions Andre et al and Sander et al since both of them teach compositions for producing vasodilating effect individually in the art. Since both of the compositions yielded beneficial results in pharmaceutical industry, one of ordinary skill in the art would have been motivated to make the modifications. The result-effective

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adjustment in conventional working parameters (e.g., determining an appropriate amount of the components within the composition) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Claims 1-10, and 15-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Andre et al (WO 200296441), in view of Sander et al (US 6,335,039), further in view of Kowey et al (Cardiovascular Research, 17: 106-112, 1982).

Andre et al teach a method of using *Trichilia catigua*, *Paullinia cupana*, *Zingiber officinale* and a carrier (excipient) as vasodilators (page 2, lines 10-15).

Andre et al do not teach treating ventricular fibrillation explicitly, neither do they teach *Croton moritibensis*.

Sander et al teach a method for producing vasodilation using 2-15% muirapuama (the same as *Croton moritibensis*, see the instant application, page 2, lines 10-15), *Trichilia catigua*, and guarana (the same as *Paullinia cupana*, see the instant specification, page 2, 2<sup>nd</sup> paragraph) (col 4, lines 15-45).

Kowey et al teach that vulnerability to ventricular fibrillation is affected by changes in systemic arterial blood pressure. Small doses of a vasodilator drug can abolish the enhanced ventricular vulnerability induced by norepinephrine, and can augment ventricular electrical stability (see Abstract).

Therefore, it would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to use *Croton moritibensis* in Sander together with *Trichilia catigua*, *Paullinia cupana*, and *Zingiber officinale* in Andre et al to treat ventricular fibrillation since Kowey et al teach that ventricular fibrillation could be abolished by pretreatment of vasodilators (see Abstract); both of inventions of Andre et al and Sander yielded beneficial results in producing vasodilation in pharmaceutical industry, one of ordinary skill in the art would have been motivated to make the modifications. The dosages of *Trichilia catigua*, *Paullinia cupana*, *Zingiber officinale* described in Andre et al (page 4, lines 5 to the bottom of the page) and the dosage of *Croton moritibensis* in Sander meet claims 4 and 5.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

### **Conclusion**

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

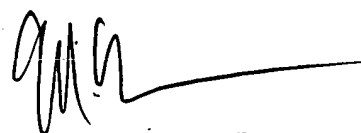
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Qiuwen Mi whose telephone number is 571-272-5984. The examiner can normally be reached on 8 to 5.



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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry Mckelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

A handwritten signature in black ink, appearing to read 'M. Meller', with a long horizontal line extending to the right.

**MICHAEL MELLER  
PRIMARY EXAMINER**